Decree of the President of the Egyptian Drug Authority No. (343) of 2021 Concerning Issuing the Rules of Biological Products' Registration Promulgating

President of Egyptian Drug Authority,

Having perused

- Law No. (127) of 1955 on Pharmacy Profession practice;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;
- Arab Republic of Egypt President's Decree No. (18) of 2020 concerning the Constitution of the Board of Directors of the Egyptian Drug Authority;
- Ordinance of the Minister of Health and Population No. (297) of 2009 on the Rules and Procedures of Registering Biological Products, antisera, Vaccines and Blood Products;
- Memorandum submitted by the Head of the Central Administration of Biological and Innovative Products and Clinical Trials;
- Material presented by the Vice President of the Egyptian Drug Authority;
- Having considered the interest of work;

Decided

(Article One)

This decree shall be implemented with respect to registration of biological products. For the purposes of its provisions, the following terms shall have the meanings set out for each term hereunder:

Biological Products: They are products that contain one or more active ingredient produced or extracted from biological origin. For instance, they may include human vaccines, antisera, blood products and plasma derivatives, biotechnology-manufactured products and the like as well any products or materials that may be created according to science developments and/or international standards and references.

Locally-Manufactured Products: They are biological products manufactured in factories inside the Arab Republic of Egypt or the products imported in bulk that are manufactured in the Arab Republic of Egypt.

Imported products: It is the imported biological products weather fully manufactured overseas or manufactured overseas and packaged in factories within the Arab Republic of Egypt.

(Article Two)

Products registered in accordance with the provisions of this decree shall be granted Marketing Authorization License valid for five years. These products shall be re-registered during the last year of the Marketing Authorization License validity.

President of the Egyptian Drug Authority has the right to issue a reasoned decree to suspend or nullify the track of registration procedures or to withdraw the Marketing Authorization License of any biological product which he deems that its circulation may be harmful to public health.

(Article Three)

The Marketing Authorization License of the product shall be annulled if the said product is not continuously and readily available on the market for one and a half year after issuing the final Marketing Authorization License. The annulment shall take effect by a resolution issued by the Head of the Central Administration of Biological and Innovative Products and Clinical Trials.

Any batch produced after the date of annulment shall be sealed and necessary disciplinary actions shall be taken in this regard.

(Article Four)

In emergency circumstances, a product may be distributed and excepted from some conditions required for registration if the Vice President of the Egyptian Drug Authority makes a recommendation which is approved by the President of the Authority.

In such a case, a sample of that product shall be withdrawn and analyzed by the Central Administration of Biological and Innovative Products and Clinical Trials. Moreover, the applicant shall present the Marketing Authorization File within two months from the approval date of the President of Egyptian Drug Authority.

(Article Five)

A biological product that has never been registered in accordance with to provisions of the above- mentioned Ordinance of the Minister of Health and Population No. (297) of 2009 shall be re- registered after the said product is analyzed for registration and the Common Technical Document file is completely assessed.

(Article Six)

Ordinance of the Minister of Health and Population No. (297) of 2009 on the Rules and Procedures of Registering Biological Products, antisera, Vaccines and Blood Products as well as any other provisions that may contradict this DECREE shall be nullified.

(Article Seven)

The Head of the Central Administration of Biological and Innovative Products and Clinical Trials shall issue a regulatory guideline of the mechanisms and procedures necessary for the implementation of this DECREE within five working days.

(Article Eight)

This DECREE shall be published in Egyptian Gazette 'the Egyptian Chronicles' and shall come into effect from the day following its publication therein.

President

Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Written on 29/7/2021